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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,671	12/12/2003	Seth A. Foerster	END-897DIV3	6289
21984 7590 11/07/2008 WELSH & FLAXMAN LLC 2000 DUKE STREET, SUITE 100 ALEXANDRIA, VA 22314				
EXAMINER				
HOEKSTRA, JEFFREY GERDEN				
ART UNIT		PAPER NUMBER		
3736				
MAIL DATE		DELIVERY MODE		
11/07/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,671

Applicant(s)

FOERSTER ET AL.

Examiner

JEFFREY G. HOEKSTRA

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Prosecution Reopened Following Appeal Brief

1. In view of the Appeal Brief filed on 07/15/2008, PROSECUTION IS HEREBY REOPENED. The following new and/or reiterated grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

Potential Interference

2. The Examiner notes as indicated in Applicant's Arguments filed 12/12/2003 and in the Office Action mailed 08/24/2007 claim 49 is copied in it's entirety from Burbank et al. (US 6,567,689).

Priority

3. Applicant states that this application is a divisional application of the prior-filed application(s). Applicant, in amendments to the Specification filed 12/12/2003 concurrently with the transmittal of the new application, states:

a. *"This divisional application claims priority to US Patent Application Serial Number 10/213,638 filed August 7, 2002, which claims priority to US Application 09/954,646 filed Sept. 18, 2001, which is a continuation of US Application 09/776,125 filed February 2, 2001, which is a continuation of US Application 08/858,389 filed May 19, 1997, which is a continuation of US Application 08/308,097 filed September 16, 1994."*

4. A divisional application cannot include new matter. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

5. Applicant, in amendments to the claims filed 12/12/2003 concurrently with the transmittal of the instant application, claimed *inter alia*:

b. *"49. (new) A delivery system for delivering marker material to a target site within a patient, comprising: an elongate member having a distal end, a*

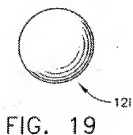
discharge port in the distal end and an inner lumen extending therein to and in fluid communication with the discharge port in the distal end; a mass of solid particulate marker material disposed within the inner lumen; and an ejector which is advancable with and coupled to said elongate member and which is configured to eject particulate marker material from the discharge port in said distal end of said elongate member."

6. The disclosure of the prior-filed application(s), US Patent Application Serial Number 10/213,638 filed August 7, 2002, which claims priority to US Application 09/954,646 filed Sept. 18, 2001, which is a continuation of US Application 09/776,125 filed February 2, 2001, which is a continuation of US Application 08/858,389 filed May 19, 1997, which is a continuation of US Application 08/308,097 filed September 16, 1994, fail(s) to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

7. Claim 49, as filed, positively recites "a mass of solid particulate marker material disposed within the inner lumen". The disclosures of the prior-filed applications do not discuss, teach, and/or show "a mass of solid particulate marker material disposed within the inner lumen".

8. Applicant in purported support of the apparent benefit for this amendment argued (see page 6 filed 12/12/2003):

- c. *"Support is also found at page 22, lines 20-27 which discloses small beads or pellets having a diameter of about 500 microns; and page 9, lines 22 which discloses marker materials including non-metallic materials and salts. It is respectfully urged that disclosure of "small beads or pellets" and "salt" provide support for claims directed to the "particulate marker material" and "powder" as those terms are used in the claims of US 6,567,689 and US 2002/0188196."*
9. The citations of the apparent support refer to page 22 lines 20-27 of the instant Specification. The Specification page 22 line 20 - page 23 line 1 reads in its entirety as follows:
- d. *"Marker elements of many other materials and configurations may be used as well. For example, one such multi-appendaged jack-shaped marker 12h is illustrated in Fig. 18. Additionally, small beads 12i (Fig. 19) of calcium carbonate or other radiodense materials, which are highly visible by mammographic imaging, could be deployed as marker elements. One such application would be to place a plurality of such beads or pellets (each having a diameter of about 500 μ) around the entirety of a breast lesion prior to the extraction procedure, which would then serve as guides to ensure that all of the margins had been removed. During subsequent imaging procedures, they would function to denote the location of the previous biopsy for reference purposes."*
10. The citations of the apparent support also refer to Figure 19. Figure 19 shows:



e.

11. The Examiner notes Figure 19, to which the Specification refers to as the "small beads... of calcium carbonate or other radiodense materials, which are highly visible by mammographic imaging, could be deployed as marker elements", apparently and solely shows a single sphere labeled 12i. The Examiner contends Figure 19 does not show or support "small beads" nor "a plurality of such beads or pellets".

12. The Examiner maintains **neither the text nor Figures of instant Specification nor the prior-filed Applications support the positive recitation of "a mass of solid particulate marker material disposed within the inner lumen" and more precisely "a mass of solid particulate marker material".**

13. Conversely, the instant disclosure and prior-filed applications do appear to be entitled to the benefit of "a plurality of small beads or pellets comprising calcium carbonate or other radiodense materials, which are highly visible by mammographic imaging, could be deployed as marker elements". Nonetheless, neither a single bead (see Figure 19 above), "small beads", nor "a plurality of small beads or pellets" apparently comprise "a mass of solid particulate marker material". Moreover it does not appear a single bead (see Figure 19 above), "small beads", and/or "a plurality of small

beads or pellets" necessarily comprise a "a mass of solid particulate marker material". In fact none of the contested disclosures appear to discuss or show "a mass" or "a solid particulate marker material" or "a mass of solid particulate marker material".

14. Thus, claim 49 does not appear entitled to the benefit of the prior-filed applications and as such is being treated on the merits as having an effective filing date of 12/12/2003. Applicant is required to change the relationship, divisional application, to continuation-in-part because this application contains the discussed subject matter not disclosed in the prior-filed application.

Drawings

15. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a mass of solid particulate marker material" and/or "a mass of solid particulate marker material disposed within the inner lumen" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

16. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
19. Claim 49 positively recites "a mass of solid particulate marker material disposed within the inner lumen". The instant Specification does not discuss, teach, and/or show "a mass of solid particulate marker material disposed within the inner lumen" in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20. Applicant in purported support of claim 49 in the instant Specification argued (see page 6 filed 12/12/2003):

f. "Support is also found at page 22, lines 20-27 which discloses small beads or pellets having a diameter of about 500 microns; and page 9, lines 22 which discloses marker materials including non-metallic materials and salts. It is respectfully urged that disclosure of "small beads or pellets" and "salt" provide support for claims directed to the "particulate marker material" and "powder" as those terms are used in the claims of US 6,567,689 and US 2002/0188196."

21. The citations of the apparent support refer to page 22 lines 20-27 of the instant Specification. The Specification page 22 line 20 - page 23 line 1 reads in its entirety as follows:

g. "Marker elements of many other materials and configurations may be used as well. For example, one such multi-appendaged jack-shaped marker 12h is illustrated in Fig. 18. Additionally, small beads 12i (Fig. 19) of calcium carbonate or other radiodense materials, which are highly visible by mammographic imaging, could be deployed as marker elements. One such application would be to place a plurality of such beads or pellets (each having a diameter of about 500 μ) around the entirety of a breast lesion prior to the extraction procedure, which would then serve as guides to ensure that all of the margins had been

removed. During subsequent imaging procedures, they would function to denote the location of the previous biopsy for reference purposes."

22. The citations of the apparent support also refer to Figure 19. Figure 19 shows:



FIG. 19

h.

23. The Examiner notes Figure 19, to which the Specification refers to as the "small beads... of calcium carbonate or other radiodense materials, which are highly visible by mammographic imaging, could be deployed as marker elements", apparently and solely shows a single sphere labeled 12i. The Examiner contends Figure 19 does not show or support "small beads" nor "a plurality of such beads or pellets". Nonetheless as described in the Specification, neither a single bead (see Figure 19 above), "small beads", nor "a plurality of small beads or pellets" apparently comprise "a mass of solid particulate marker material". Moreover it does not appear a single bead (see Figure 19 above), "small beads", and/or "a plurality of small beads or pellets" necessarily comprise a "a mass of solid particulate marker material".
24. The Examiner maintains neither the text nor Figures of instant Specification support the positive recitation of "a mass of solid particulate marker material disposed within the inner lumen" in claim 49 and as such is fails to comply with the written description requirement.

Claim Rejections - 35 USC § 102

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

26. Claim 49, with an effective filing date of 12/12/2003, is rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al. (US 2002/0161298 A1 published 10/31/2002, now US 6,567,689 B2 issued 5/20/2003, and hereinafter Burbank).

27. For claim 49, Burbank discloses a delivery system (100) for delivering marker material to a target site within a patient (as best seen in Figures 3-4) (paragraphs 90-97), comprising:

- an elongate member (tubular barrel element 110 as seen in Figure 4) having a distal end (the left end of tubular barrel element 110 as seen in Figure 4), a discharge port in the distal end (the open left end of tubular barrel element 110 as seen in Figure 4) and an inner lumen (the inner lumen of tubular barrel element 110 as seen in Figure 4) extending therein to and in fluid communication with the discharge port in the distal end (as seen in Figure 4);
- a mass of solid particulate marker (10) material disposed within the inner lumen (as best seen in Figures 3-4) (paragraphs 90-97); and
- an ejector (114) which is advancable with and coupled to said elongate member (as seen in Figure 4) and which is configured to eject particulate marker material from

the discharge port in said distal end of said elongate member (as seen in Figures 3-4) (paragraphs 90-97).

28. Claim 49 is rejected under 35 U.S.C. 102(b) as being anticipated by Burton (US 3,741,198 issued 06/26/1973).

29. For claim 49, Burton discloses a delivery system for delivering marker material to a target site within a patient (Abstract, column 3 line 63 – column 6 line 57) (as best seen in Figures 1, 3, and 6), comprising:

- an elongate member (puncture needle 14) (column 4 line 66 – column 5 line 17 and column 6 lines 50-57) having a distal end (the insertion/inserted end of puncture needle 14 as best seen in Figures 1, 3, and 6), a discharge port in the distal end (the open distal end of puncture needle 14 as best seen in Figures 3 and 6) and an inner lumen (the inner lumen of puncture needle 14 as best seen in Figures 3 and 6) extending therein to and in fluid communication with the discharge port in the distal end (as best seen in Figures 3 and 6);
- a mass of solid particulate marker (28) material disposed within the inner lumen (as best seen in Figures 3-4) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17); and
- an ejector (the syringe positively recited in column 5 lines 12-15) which is advancable with and coupled to said elongate member (column 5 lines 12-15) and which is configured to eject particulate marker material from the discharge port in said distal end of said elongate member (the injection of the marker material through

the puncture needle via use of the syringe as positively recited in column 5 lines 12-15).

Response to Arguments

30. Applicant's arguments with respect to claim 49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

31. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Preissman (US 6,231,615 B1) discloses the injection of a mass of solid particulate marker material into a target site of a patient through an elongate member.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736